



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,612	09/15/2003	Gust H. Bardy	1201.1101102	2346
21691 7590 03/08/2007 CROMPTON SEAGER AND TUFTE, LLC 1221 NICOLLET AVENUE SUITE 800 MINNEAPOLIS, MN 55403-2420			EXAMINER MULLEN, KRISTEN DROESCH	
			ART UNIT	PAPER NUMBER
			3766	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/662,612	Applicant(s) BARDY ET AL.	
	Examiner Kristen Droesch Mullen	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12/5/06 (Response).
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 38, 40, 42 and 44-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 40, 42, 44, 45 and 50 is/are allowed.
- 6) ☒ Claim(s) 1, 38, 46-49 and 51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1 and 46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites electrical cardioversion-defibrillation energy from about 3 Volts to about 2000 Volts. This is inaccurate because the specification discloses (as originally filed in the parent application) electrical cardioversion-defibrillation energy from about 800V to 2000V, and a fibrillation induction voltage of 3 Volts.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 49 and 51 are rejected under 35 U.S.C. 102(b) as being anticipated by Hauser et al. (5,385,574).

Regarding claim 49, Hauser shows an implantable unitary subcutaneous cardioverter-defibrillator with an implantable canister providing a long (height in Figs.) thin (depth in Figs.) curved housing (see curved edges) enclosing and containing cardioversion-defibrillation circuitry, a pair of electrodes (70 or 62, 64) formed on opposite and facing ends of the housing

Art Unit: 3766

and electrically interfaced via one or more conductors to the cardioversion-defibrillation circuitry and pacing circuitry (Figs. 8, 11, 16; Col. 5, lines 27-39; Col. 7, lines 7-15, 25-35).

With respect to claim 51, Hauser shows an implantable unitary subcutaneous cardioverter-defibrillator with an implantable canister providing a curved housing (see curved edges) enclosing and containing cardioversion-defibrillation circuitry, a pair of electrodes (70 or 62, 64) formed on opposite and facing ends of the housing and electrically interfaced via one or more conductors to the cardioversion-defibrillation circuitry and detection circuitry (84) and the detection circuitry and cardioversion defibrillation circuitry are programmable (Col. 5, lines 31-36; Col. 6, lines 22-25; Col. 7, lines 29-35; Figs. 8, 11, 16).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hauser et al. (5,385,574) in view of Kroll (5,643,323).

Hauser shows a canister comprising a biocompatible housing enclosing and containing cardioversion-defibrillation circuitry, said housing having first and second ends, wherein the first end (bottom portion) is thicker than the second end (header portion) (Figs. 9, 11) a pair of electrodes (70 or 62, 64) formed on opposite ends of the housing and electrically interfaced to the cardioversion-defibrillation circuitry (Figs. 8, 11, 16).

Although Hauser fails to show the circuitry is configured to deliver a low voltage of

Art Unit: 3766

about 3 volts, attention is directed to Kroll which teaches implantable defibrillators with induction circuitry that deliver low voltage (of about 5 Volts) are useful to determine the defibrillation threshold for an implantable defibrillator (Col. 1, line 14-Col. 2, line 62).

Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the device of Hauser to include induction circuitry that generates low amplitude voltage on a T-wave as Kroll teaches in order to enable defibrillation threshold testing.

Hauser and Kroll fail to explicitly teach that voltage is about 3 Volts. It would have been obvious to one with ordinary skill in the art at the time of the invention to utilize a low voltage of 3V in the apparatus of Hauser and Kroll since the use of 3V is a result effective variable that can be determined by routine experimentation by one with ordinary skill in the art. It has been held by our reviewing courts that it is within the level of ordinary skill in the art to discover an optimum value of a result effective variable. See MPEP 2144.05 and *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA, 1980).

7. Claims 46-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hauser et al. (5,385,574) in view of Ostroff (5,215,081). Hauser shows an implantable unitary subcutaneous cardioverter-defibrillator with an implantable canister providing a curved housing (see curved edges) enclosing and containing cardioversion-defibrillation circuitry, a pair of electrodes (70 or 62, 64) formed on opposite and facing ends of the housing and electrically interfaced via one or more conductors to the cardioversion-defibrillation circuitry (Figs. 8, 11, 16). Although Hauser fails to specify the desirable range of voltages, energies (Joules), shock duration, and capacitance, attention is directed to Ostroff who teaches that the cardioversion-

Art Unit: 3766

defibrillation energy is directly related to capacitance, shock duration, voltage, and resistance of the electrodes which in turn is dependent on electrode position and integrity (Col. 5, lines 50-56).

It would have obvious to one with ordinary skill in the art at the time the invention was made to utilize the range of voltages, energies (Joules), shock durations, and capacitances set forth in the claim, since it is well known in the art that these factors are related to one another, and the ultimate energy delivered to the heart is dependent on these factors along with the resistance measured between the electrodes.

8. Claim 48 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hauser et al. (5,385,574) in view of Kroll (5,709,709). Hauser shows an implantable unitary subcutaneous cardioverter-defibrillator with an implantable canister providing a curved housing (see curved edges) enclosing and containing cardioversion-defibrillation circuitry, a pair of electrodes (70 or 62, 64) formed on opposite and facing ends of the housing and electrically interfaced via one or more conductors to the cardioversion-defibrillation circuitry and monitoring circuitry (84) integral with the cardioversion-defibrillation circuitry and which derives physiological measures relating to QRS R-R interval stability (Col. 5, lines 27-39; Col. 6, lines 18-20, 22-25; Col. 7, lines 29-34; Figs. 8, 11, 16). Although Hauser fails to shows monitoring circuitry is configured to monitor respiration, attention is directed to Kroll who shows an implantable cardioverter/defibrillator which monitors respiration so that the ICD can provide rate responsive pacing dependent on respiration. Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the device of Hauser to include monitoring circuitry is configured to monitor respiration as taught by Kroll in order to enable the capability of providing rate responsive pacing dependent on respiration.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1, 46-47 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 3 (which includes the limitations of claims 1-2) and claim 99 (which includes the limitation of claim 95) of U.S. Patent No. 6,647,292

For double patenting to exist as between the rejected claims and the patent claims, it must be determined that the rejected claims are not patentably distinct from claims 3 and 99. In order to make this determination, it first must be determined whether there are any differences between the rejected claims and claims 3 and 99 and, if so, whether those differences render the claims patentably distinct.

The difference between claims 1 and 46-47 of the application and claims 3 and 99 of the patent lies in the fact that the patent claim includes many more elements and is thus much more specific.

It is clear that all the elements of claims 1 and 46-47 are to be found in claims 3 and 99 (as they encompasses claims 1-2 and 95). Thus, the invention of claims 1 and 46-47 of the patent is in effect a “species” of the “generic” invention of claims xxx of the application. It has been held that the generic invention is “anticipated” by the “species”. See *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993). Since claims 1 and 46-47 are anticipated by claims 3 and 99 of the patent, they are not patentably distinct from claims 3 and 99.

Allowable Subject Matter

11. Claims 40, 42, 44-45 and 50 are allowed.

Response to Arguments

12. Applicant's arguments with respect to claims 1, 38, 46-49 and 51 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

Art Unit: 3766

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen Droesch Mullen whose telephone number is (571) 272-4944. The examiner can normally be reached on M-F, 10:30 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Kristen Droesch Mullen
Patent Examiner
Temp. Signatory Authority
Art Unit 3766

kdm